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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/684,883 | 10/06/2000 | Bernard R. Brodeur | 047998/0197 | 3090 |

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01/16/2002

Foley & Lardner
Washington Harbour
3000 K Street N W
Suite 500
Washington, DC 20007-5109

EXAMINER

GRASER, JENNIFER E

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 01/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/684,883

Applicant(s)

Brodeur et al.

Examiner

Jennifer Graser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-169 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 91-169 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

Sequence Compliance

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2).

However, this application fails to comply with the requirements of 37 C.F.R. 1.821-25 for the reasons set forth on the attached Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant should follow the format of the attached sample statement to request that the CRF filed in the parent application be used to create a CRF in this application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 91-94, 104-106 and 116-123, drawn to isolated polynucleotides relating to SEQ ID NO:1, classified in class 536, subclass 23.7.
- II. Claims 91, 95-97, 107-109 and 116-123, drawn to isolated polynucleotides relating to SEQ ID NO:3, classified in 536, subclass 23.7.
- III. Claims 91, 98-100, 110-112 and 116-123, drawn to isolated polynucleotides relating to SEQ ID NO:5, classified in 536, subclass 23.7.
- IV. Claims 91, 101-103, 113-115 and 116-123, drawn to isolated polynucleotides relating to SEQ ID NO:7, classified in 536, subclass 23.7.

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- V. Claims 124-130 and 133-137, drawn to polypeptides, classified in class 530, subclass 350.
 - VI. Claims 131 and 132 drawn to a method of isolating a polypeptide, classified in class 530, subclass 412.
 - VI. Claims 138-148, drawn to antibodies, classified in class 530, subclass 387.1.
 - VII. Claims 149-154, drawn to pharmaceutical compositions comprising an antibody and methods of treating a patient through the administration of said antibody, classified in class 424, subclass 130.1.
 - VIII. Claims 155-157, drawn to a method of detecting Neisseria antigen by incubating an antibody with a biological sample, classified in class 435, subclass 7.1.
 - IX. Claims 158-160, drawn to a method for detecting an antibody by incubating an antigen with a biological sample, classified in class 435, subclass 7.92.
 - IX. Claims 161-162, drawn to a method of in vivo detection, classified in class 424, subclass 9.1.
 - X. Claims 163-169, drawn to methods of detection via hybridization (Note: only one SEQ ID No. and its fragments will be examined. Applicant must choose one if this Group is elected), classified in class 435, subclass 6.
3. The inventions are distinct, each from the other because of the following reasons:
- Groups I-IV are drawn to different products with different structures. These polynucleotides encode completely different proteins. Accordingly, these polynucleotides are

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patentably distinct and independent from one another. Groups I-IV, V and VI are drawn to biologically, chemically, and structurally different products and are therefore patentably distinct from one another.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies may be used in a materially different process than in passive immunization procedures, i.e., the antibodies may be used as diagnostics.

Inventions V and VIII or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies may be used in a materially different process than in a detection method, i.e., the antibodies may be used as therapeutics such as in passive immunization procedures. Additionally, the methods of VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, have different modes of operation because one method involves taking a sample from a patient and the other method involves in

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vivo testing. These are very different methods which involve different method steps and reagents.

Inventions V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides may be used in methods other than detection, i.e., they may be used in immunization methods.

Inventions I-V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides may be used for other methods than hybridization, i.e., they may be used to produce recombinant proteins or in recombinant vaccines.

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of making the proteins can be made in a manner different than that recited in claims 131 and 132, i.e., the proteins may be made synthetically.

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Because the inventions of Groups I-VI are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the literature search for the Groups is not coextensive, restriction for examination purposes as indicated is proper.

4. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Graser 1/15/02
JENNIFER E. GRASER
PRIMARY EXAMINER

Sample Statement

Sample Request to Use Computer Readable Form from Another Application

The following paragraph, or language having the same effect, can be used to invoke the procedures of 37 CFR section 1.821(e) in which an identical computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application:

The computer readable form in this application, 08/100,000, is identical with that filed in Application Number 07/999,999, filed March 1, 1988. In accordance with 37 CFR 1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].